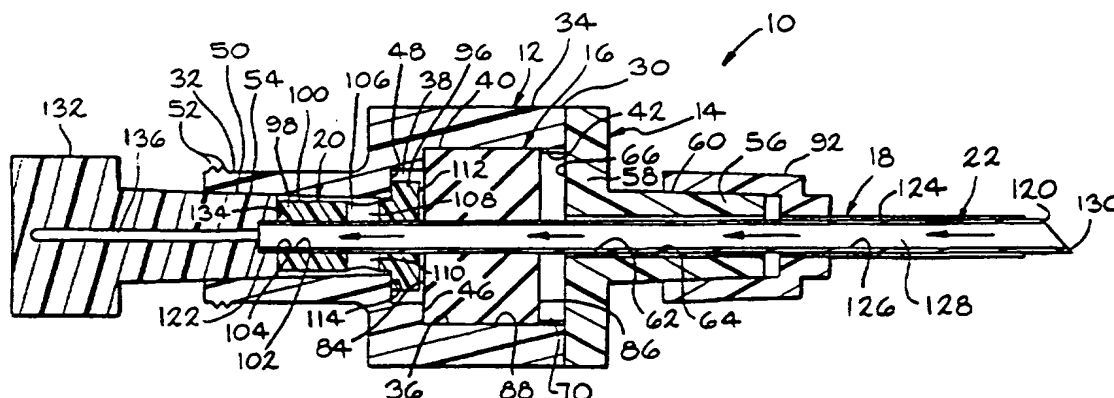




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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**(54) Title:** VALVE ASSEMBLY FOR MEDICAL USES**(57) Abstract**

A valve assembly having a body, an end cap, a resilient septum, and an actuator. The body forms a plurality of fluid recesses. The end cap defines a plurality of projections that form channels. The septum is positioned between the body and the end cap. An actuator device is positioned adjacent the septum for moving the septum away from a shoulder defined in the body to allow fluid to pass through the body, actuator, and end cap. The assembly can include a sharp. The sharp extends through the body, the actuator, the septum and the end cap.

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## DESCRIPTION

### VALVE ASSEMBLY FOR MEDICAL USES

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#### BACKGROUND OF THE INVENTION

The present invention is related to a valve assembly. More specifically, the invention is directed to a valve assembly for use in the regulation of fluid flow to and from a blood vessel.

Valve assemblies for various medical uses are known in the art. Examples of such assemblies are disclosed in U.S. Patent Nos. 4,254,773; 4,683,916; 5,171,230; 5,242,393; and 5,405,323.

It has been found that there is a need for a valve assembly that provides a superior seal within the assembly to prevent leakage. There is also a need for a valve assembly that can be used with a sharp. Examples of sharps include needles and trocars. The present invention satisfies the above-identified needs.

#### SUMMARY OF THE INVENTION

The present invention is directed to a valve assembly having a body. The body has a first end, a second end, an exterior surface and an interior surface. The interior surface defines a body fluid passageway extending between the first and second ends. The interior surface defines a chamber having a cylindrical side wall adjacent the first end. The cylindrical side wall defines a plurality of fluid recesses. The interior surface defines an annular septum shoulder adjacent the cylindrical side wall.

An end cap is positioned adjacent the first end of the body. The end cap is in communication with the chamber of the body. The end cap has an attachment end, a body end, an outer surface and an inner surface. The inner surface defines an end cap fluid passageway

extending between the attachment end and the body end. A catheter or intravenous (IV) luer fitting can be attached to the attachment end. The body end includes a plurality of spaced outwardly extending projections adjacent the end cap fluid passageway. The projections are adjacent the chamber of the body.

The assembly further includes a septum or seal that has a shoulder surface and an opposed projections surface. The septum has a substantially circular chamber wall extending between the shoulder and projections surfaces. The shoulder surface engages the septum shoulder of the body to form a seal when the valve is in a closed position. The projections surface engages the projections. The chamber wall is adjacent the cylindrical side wall of the chamber. The chamber wall and the fluid recesses form a plurality of chamber fluid passageways.

An actuator is positioned in the body fluid passageway adjacent the second end of the body. The actuator moves the shoulder surface of the septum away from the septum shoulder of the body to allow fluid to flow through the body fluid passageway, the chamber fluid passageways and the end cap fluid passageway.

The assembly can include a sharp, such as a needle, having a first needle end, a second needle end, a needle exterior surface and a needle interior surface. The needle interior surface defines a needle fluid passageway extending between the first needle end and the second needle end. The needle extends through the actuator, the septum and the end cap fluid passageway. If a catheter is attached to the attachment end of the end cap, the needle extends through the catheter fluid passageway.

It is the primary object of the present invention to provide a valve assembly that has a superior seal within the assembly for preventing leakage of fluid.

It is an important object of the present invention to provide a valve assembly that can be used with a sharp.

Other objects and advantages of the present invention shall become apparent to those skilled in the art upon a review of the following detailed description of the preferred embodiments and the accompanying drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a cross-sectional view taken through the center of a first embodiment valve assembly according to the present invention including a needle and a catheter;

Fig. 2 is an exploded view showing the body, septum and end cap of the present invention;

Fig. 3 is a cross-sectional view taken along line 3-3 of Fig. 7 showing the assembly according to the present invention in a sealed position;

Fig. 4 is a cross-sectional view taken along line 4-4 of Fig. 8 showing the assembly in an open position;

Fig. 5 is a cross-sectional view taken along line 5-5 of Fig. 7 showing the assembly in a sealed position;

Fig. 6 is a cross-sectional view taken along line 6-6 of Fig. 8 showing the assembly in an open position;

Fig. 7 is a cross-sectional view taken along line 7-7 of Fig. 3;

Fig. 8 is a cross-sectional view taken along line 8-8 of Fig. 4;

Fig. 9 is a cross-sectional view taken through the center of a second embodiment of the valve assembly according to the present invention including a catheter;

Fig. 10 is a view similar to the view of Fig. 9 further including a needle;

Fig. 11 is a view similar to the view of Fig. 9 showing the assembly in an open position;

Fig. 12 is a perspective view of a second embodiment actuator;

Fig. 13 is a perspective view of a second embodiment body;

5 Fig. 14 is a perspective view of a second embodiment end cap;  
and

Fig. 15 is a cross-sectional view taken through the center of the second embodiment assembly including a needle, needle guard assembly and catheter.

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#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The preferred embodiments and best mode of the present invention shall now be described in detail with reference being made to the accompanying drawings. The valve assembly of the present invention is indicated generally in the drawings by the reference number "10". As shown in Fig. 1, the assembly 10 includes a body 12, an end cap 14, a septum 16 and an actuator 20. Depending on the use of the present invention, the assembly 10 can also include a catheter 18 and a sharp, such as a needle 22. Referring to Figs. 1 and 2, the body 12 has a first end 30, a second end 32, an exterior surface 34 and an interior surface 36. The interior surface 36 defines a body fluid passageway 38 extending between the first and second ends 30 and 32. The interior surface 36 defines a chamber 40 having a cylindrical side wall 42 adjacent the first end 30. As shown in Figs. 2, 5 and 7, the cylindrical side wall 42 defines a plurality of fluid recesses 44. In the present embodiment, there are four fluid recesses 44 defined by the cylindrical side wall 42. It should be understood that any number of fluid recesses 44 can be defined by the side wall 42. As shown in Fig. 1, the interior surface 36 defines an annular septum shoulder 46 adjacent the chamber 40 of the body 12. The interior surface 36 further defines an annular

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actuator shoulder 48 adjacent the septum shoulder 46 in the body fluid passageway 38.

Referring now to Figs. 1, 2 and 4, the exterior surface 34 of the body 12 includes a luer attachment fitting 50. The luer attachment fitting 50 includes luer attachment members 52 and a luer tapered fitting 54. The luer attachment fitting 50 is positioned on the second end 32 of the body 12. The luer attachment fitting 50 can be the type set forth in American National Standard Institute No. ANSI/HIMA MD70.1 - 1983.

As shown in Figs. 1 and 2, the end cap 14 is positioned adjacent the first end 30 of the body 12. The end cap 14 is in communication with the chamber 40 of the body 12. The end cap 14 has an attachment end 56, a body end 58, an outer surface 60 and an inner surface 62. The inner surface 62 defines an end cap fluid passageway 64 that extends between the attachment end 56 and the body end 58.

Referring to Fig. 2, the body end 58 of the end cap 14 includes an annular face 66. The opening 68 of the end cap fluid passageway 64 is positioned in the center of the annular face 66. A plurality of spaced outwardly extending projections 70 are positioned on the annular face 66. In the present embodiment, there are four projections 70. Each of the projections 70 is in the shape of a sector having first and second equidistant sides 72 and 74, and an arc 76. The arcs 76 of the projections 70 generally define a circle with the center of the circle being the opening 68. The projections 70 encompass the opening 68. As shown in Fig. 2, the projections 70 define a plurality of channels 78. In the present embodiment, four channels 78 are defined by the four projections 70. As described below, the channels 78 are used to channel fluid to the opening 68. As shown in Figs. 1, 2 and 6, the projections 70 are positioned in the chamber 40 adjacent the cylindrical side wall 42 of the body 12. The projections 70 are positioned so that the channels 78

are in communication with the fluid recesses 44. As shown in Fig. 2, each of the projections 70 includes a flat septum surface 80.

Referring now to Figs. 1, 2, 7 and 8, the septum 16 has a shoulder surface 84 and an opposed projections surface 86. A circular chamber wall 88 extends between the shoulder and projections surfaces 84 and 86. The shoulder surface 84 engages the septum shoulder 46 defined by the body 12 to form a seal when the assembly 10 is in a sealed position. The projections surface 86 engages the septum surfaces 80 of the projections 70. The septum surfaces 80 provide flat surfaces upon which the septum 16 can be seated.

As shown in Figs. 7 and 8, the chamber wall 88 of the septum 16 is positioned adjacent the cylindrical side wall 42 and fluid recesses 44 of the chamber 40. When so positioned, the chamber wall 88 and the fluid recesses 44 form a plurality of chamber fluid passageways 90. In the present embodiment, four chamber fluid passageways 90 are formed.

The septum 16 is made of a resilient, compressible elastomeric material. The septum 16 should be made of a material that can be compressed or deformed numerous times without losing its original shape. The material used should also allow the septum 16 to be pierced by a sharp, such as a needle 22, as described below, and be self-sealing after removal of the sharp. An example of a material that can be used to make the septum 16 is a biocompatible synthetic polymer material.

As shown in Fig. 1, the catheter 18 is positioned on the attachment end 56 of the end cap 14 by a catheter fitting 92. The catheter fitting 92 can be the type set forth in American National Standard Institute No. ANSI/HIMA MD70.1-1983. The catheter 18 can also be directly attached to the end cap 14 (not shown). As shown in Fig. 3, a catheter fluid passageway 94 extends through the catheter 18.

Referring to Figs. 1, 3 and 4, the actuator 20 includes a first actuator end 96, a second actuator end 98, an exterior actuator surface



100 and an interior actuator surface 102. The interior actuator surface 102 defines an actuator fluid passageway 104 extending between the first actuator end 96 and the second actuator end 98. The actuator 20 further includes a second fluid passageway 106 that extends  
5 perpendicular to the first actuator fluid passageway 104. The second actuator fluid passageway 106 consists of openings 108 and 110 that each extends from the interior actuator surface 102 to the exterior actuator surface 100. As shown in Figs. 3 and 4, the actuator exterior surface 100 defines an annular septum contact surface 112 and an  
10 opposed actuator shoulder contact surface 114. The septum contact surface 112 engages the shoulder surface 84 of the septum 16. The actuator shoulder contact surface 114 engages the actuator shoulder 48 of the body 12. The actuator 20 is positioned in the body fluid passageway 38 adjacent the second end 32 of the body 12.

15 Referring to Fig. 1, the needle 22 includes a first needle end 120, a second needle end 122, a needle exterior surface 124 and a needle interior surface 126. The needle interior surface 126 defines a needle fluid passageway 128 extending between the first needle end 120 and the second needle end 122. The needle 22 includes a sharp point 130  
20 at the first needle end 120. During the manufacture of the assembly 10, the point 130 pierces the septum 16 to allow the needle 22 to be inserted through the septum. When the assembly 10 is used, the point 130 is used to pierce the skin and blood vessel of a patient. A handle 132 is positioned adjacent the second needle end 122. The handle 132  
25 includes an actuator end 134 adjacent the second actuator end 98 of the actuator 20. The handle 132 includes an indicator channel 136 that is in communication with the needle fluid passageway 128. The handle 132 can be made of a transparent material, such as clear plastic. The handle 132 is transparent so that one using the assembly 10 can readily  
30 see blood or other fluid once the needle 22 is properly inserted. As

shown in Fig. 1, the needle 22 extends through the actuator fluid passageway 104, the septum 16, the end cap fluid passageway 64 and the catheter fluid passageway 94.

5 The use of the assembly 10 of the present invention will now be described. Referring to Figs. 1 and 3 through 8, one using the assembly 10 locates a blood vessel on a patient's body. The point 130 of the needle 22 and the catheter 18 are inserted through the skin and blood vessel of the patient. Once the needle 22 is in the blood vessel, blood "flashes" through the needle fluid passageway 128, in the direction  
10 shown by the arrows in Fig. 1, to the indicator channel 136 of the handle 132. Once blood is seen in the indicator channel 136, the needle 22 is removed from the assembly 10 by pulling the handle 132 away from the second end 32 of the body 12. In so doing, the needle 22 is removed from the catheter fluid passageway 94, the end cap fluid passageway  
15 64, the septum 16, the actuator fluid passageway 104 and the body fluid passageway 38. The needle 22 is then discarded. After removal of the needle 22 from the blood vessel, the catheter 18 remains positioned in the blood vessel.

Referring to Figs. 3 and 5, a seal is formed between the septum  
20 shoulder 46 of the body 12 and the shoulder surface 84 of the septum 16. The seal is tight because the shoulder surface 84 of the septum 16 is forced against the septum shoulder 46 due to the resilient nature of the septum and the contact of the projections surface 86 against the projections 70. Therefore, any blood flowing in the direction of the  
25 arrows shown in Fig. 3 will be prevented by the seal from escaping into the body fluid passageway 38 of the body 12. This prevents blood from exiting the second end 32 of the body 12.

Referring to Figs. 4, 6 and 8, a male luer 140, which is attached to intravenous tubing or other apparatus (not shown), can be attached  
30 to the second end 32 of the body 12. The luer 140 mates with the luer

attachment fitting 50 by rotating the luer tapered fitting 54 into the luer 140 until recesses 142 engage the luer attachment projections 52. The luer 140 includes a male member 144 that is inserted in the body fluid passageway 38. The male member 144 engages the second actuator end 98 of the actuator 20. The engagement of the male member 144 with the second actuator end 98 causes the septum contact surface 112 of the actuator 20 to engage and press against the shoulder surface 84 of the septum 16. Due to the resilient nature of the septum 82, the shoulder surface 84 becomes disengaged from the septum shoulder 46 of the body 12. This breaks the seal between the shoulder surface 84 and the septum shoulder 46. As shown by the arrows in Fig. 6, fluid is free to flow from the luer 140 through the first actuator fluid passageway 104 to the openings 108 and 110 of the second actuator fluid passageway 106 through the chamber fluid passageways 90 to the channels 78 through the end cap fluid passageway 64 and to the catheter fluid passageway 94 into the blood vessel. Fluid can also flow in the opposite direction. The assembly 10 can be resealed by removing the luer 140 from the second end 32 of the body 12 thereby causing the septum 16 to regain its original shape to form a seal between the shoulder surface 84 and the septum shoulder 46. Upon removal of the luer 140, the axial movement of the actuator 20 is restricted when the shoulder contact surface 114 engages the actuator shoulder 48 of the body 12.

The description of the assembly 10 has included a catheter 18 and a needle 22. It should be understood that the present invention can also be used as a valve in a needleless access system. In this type of system, the attachment end 56 of the end cap 14 could include a luer attachment fitting of the type set forth in American National Standard Institute No. ANSI/HIMA MD70.1-1983. This would allow the attachment end 56 to mate with a luer in communication with, for example, IV tubing. The

second end 32 of the body 12 includes a luer attachment fitting 50, as previously described, so that a luer 140 in communication with, for example, IV tubing can be attached to the body 12. When the valve assembly 10 is used in a needleless access system, fluid is free to flow from the luer 140 through the first actuator fluid passageway 104 to the openings 108 and 110 of the second actuator fluid passageway 106 through the chamber fluid passageways 90 to the channels 78 through the end cap fluid passageway 64 and to the luer attached to the attachment end 56 of the end cap 14. The assembly 10 can be resealed by removing the luer 140 from the body 12. This would cause the septum 16 to engage the septum shoulder 46 as previously described to seal the assembly 10.

A second embodiment of the valve assembly 10 of the present invention is shown in Figs. 9 through 15. Referring to Figs. 9 through 11, the second embodiment assembly 10 includes a body 212, an end cap 214, a septum 216 and an actuator 220. As shown in Fig. 10, the assembly 10 can also include a catheter 218 and a sharp, such as a needle 222. It should be understood that the assembly 10 can be used as a valve in a needleless access system without a catheter 218 or needle 222 as previously described.

Referring to Figs. 9 and 13, the body 212 has a first end 230, a second end 232, an exterior surface 234 and an interior surface 236. The interior surface 236 defines a body fluid passageway 238 extending between the first and second ends 230 and 232. The interior surface 236 defines a chamber 240 having a cylindrical side wall 242 adjacent the first end 230. As shown in Fig. 13, the cylindrical side wall 242 defines a plurality of longitudinally extending chamber members 243 that define a plurality of fluid recesses 244. In the second embodiment, there are six chamber members 243 that define six fluid recesses 244. It should be understood that any number of fluid recesses 244 can be

defined by the chamber members 243. As shown in Figs. 9 and 13, the interior surface 236 defines an annular septum shoulder 246 adjacent the chamber 240 of the body 212.

5 Still referring to Figs. 9 and 13, the exterior surface 234 of the body 212 includes a luer attachment fitting 250. The luer attachment fitting 250 includes luer attachment members 252 and a luer tapered fitting 254. The luer attachment fitting 250 is positioned on the second end 232 of the body 212.

10 Referring to Figs. 9 and 14, the end cap 214 is positioned adjacent the first end 230 of the body 212. The end cap 214 is in communication with the chamber 240 of the body 212. The end cap 214 has an attachment end 256, a body end 258, an outer surface 260 and an inner surface 262. The inner surface 262 defines an end cap fluid passageway 264 that extends between the attachment end 256 and the body end 258. As shown in Fig. 9, the attachment end 256 can include a plurality of threads 265 for receiving the catheter 218. It should be understood that the attachment end 256 can include a variety of attachment devices or fittings depending on the use of the assembly 10. For example, the attachment end 256 can include a luer attachment fitting for mating engagement with a luer.

20 As shown in Fig. 14, the body end 258 of the end cap 214 includes an annular face 266. The opening 268 of the end cap fluid passageway 264 is positioned in the center of the annular face 266. A plurality of spaced outwardly extending end cap projections 270 are positioned on the annular face 266. In the present embodiment, there are five end cap projections 270. The end cap projections 270 encompass the opening 268. The end cap projections 270 define a plurality of channels 278. In the present embodiment, five channels 278 are defined by the five end cap projections 270. The channels 278 are used to channel fluid to the opening 268. As shown in Fig. 9, the end

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cap projections 270 are positioned in the chamber 240 adjacent the cylindrical side wall 242 of the body 212. The end cap projections 270 are positioned so that the channels 278 are in communication with the fluid recesses 244. As shown in Fig. 14, each of the end cap projections  
5 270 includes a flat septum surface 280.

As shown in Fig. 9, the septum 216 has a shoulder surface 284 that defines an actuator recess 285. The septum 216 further includes a projections surface 286 that defines an end cap recess 287. A circular chamber wall 288 extends between the shoulder and projections surfaces  
10 284 and 286. The shoulder surface 284 engages the septum shoulder 246 defined by the body 212 to form a seal when the assembly 10 is in a sealed position. The projections surface 286 engages the septum surfaces 280 of the projections 270. The septum 216 is pre-loaded in the chamber 240 in order to properly seat the septum in the assembly  
15 10. As shown in Fig. 9, the positive pressure resulting from the pre-loading causes portions of the projections surface 286 of the septum 216 to extend beyond the septum surfaces 280 of end projections 270. The extending portions of the projections surface 286 do not contact the annular face 266 of the end cap 214 to interfere with the flow of fluid  
20 through the assembly 10.

As shown in Figs. 9 and 11, the chamber wall 288 of the septum 216 is positioned adjacent the cylindrical side wall 242 and fluid recesses 244 of the chamber 240. When so positioned, the chamber wall 288 and the fluid recesses 244 form a plurality of chamber fluid passageways  
25 290. In the present embodiment, six chamber fluid passageways 290 are formed.

Referring to Fig. 9, the septum 216 is made of a resilient, compressible elastomeric material. The septum 216 should be made of a material that can be compressed or deformed numerous times without  
30 losing its original shape. The material used should also allow the septum

216 to be pierced by a sharp, such as a needle 222, and be self-sealing after removal of the sharp. As previously described, an example of a material that can be used to make the septum 216 is a biocompatible synthetic polymer material.

5 Referring to Fig. 9, the catheter 218 is positioned on the attachment end 256 of the end cap 214 by a catheter fitting 292. The catheter fitting 292 includes a plurality of threads 293 that mate with the threads 265 of the end cap 214. The catheter 218 includes a catheter fluid passageway 294.

10 Referring to Figs. 9 and 12, the actuator 220 includes a first actuator end 296, a second actuator end 298, an exterior actuator surface 300, and an interior actuator surface 302. The interior actuator surface 302 defines a needle passageway 304 extending between the first actuator end 296 and the second actuator end 298. The interior  
15 actuator surface 302 defines a fluid passageway 306 adjacent the second actuator end 298. As shown in Figs. 9 and 12, the actuator exterior surface 300 defines an annular septum contact surface 312 and an opposed fitting contact surface 314. A portion of the exterior surface 300 and the septum contact surface 312 engage the actuator recess 285  
20 of the septum 216. As shown in Fig. 11, the fitting contact surface 314 engages, for example, the male member 144 of a luer 140. The actuator 220 is positioned in the body fluid passageway 238 adjacent the second end 232 of the body 212.

Referring to Fig. 10, the needle 222 includes a first needle end  
25 320, a second needle end 322, a needle exterior surface 324 and a needle interior surface 326. The needle interior surface 326 defines a needle fluid passageway 328 extending between the first needle end 320 and the second needle end 322. As shown in Fig. 10, the needle 322 extends through the needle passageway 304 of the actuator 220, the

septum 216, the end cap fluid passageway 264 and the catheter fluid passageway 294.

Referring to Fig. 15, an embodiment of a combined needle handle and guard 332 is shown. The handle 332 includes a first handle end 334 and a second handle end 336. The first end 334 is attached to the second end 232 of the body 212. The second needle end 322 of the needle 222 is attached to a reciprocating handle member 338. When the needle 222 is to be removed from the assembly 10, the handle member 338 is moved from the first end 334 of the handle 332 toward the second end 336. When the handle member 338 is adjacent the second end 336, the needle 222, including the sharp point 330, is completely retracted into the body of the handle 332. The handle 332 can then be removed from the assembly 10 and discarded. Once the handle 332 is removed, the second end 232 of the body 212 can receive, for example, a luer.

The use of the second embodiment assembly 10 of the present invention will now be described. Referring to Figs. 10 and 15, one using the assembly 10 locates a blood vessel on the patient's body. The point 330 of the needle 222 and the catheter 218 are inserted through the skin and blood vessel of the patient. Once the needle 222 is in the blood vessel, blood "flashes" through the needle fluid passageway 328, in the direction shown by the arrows in Fig. 10. The needle 222 is removed from the assembly 10 by pulling the handle member 338 toward the second end 336 of the handle 332. This causes the needle 222 to be removed from the catheter fluid passageway 294, the end cap fluid passageway 264, the septum 216, the needle passageway 304 and the body fluid passageway 238. The handle 332 is then removed from the body 212 and discarded. After removal of the needle 222 from the blood vessel, the catheter 218 remains positioned in the blood vessel.



Referring to Fig. 9, a seal is formed between the septum shoulder 246 of the body 212 and the shoulder surface 284 of the septum 216. Therefore, blood will be prevented by the seal from escaping into the body fluid passageway 238 of the body 212. This prevents blood from exiting the second end 232 of the body 212.

Referring to Fig. 11, a male luer 140 can be attached to second end 232 of the body 212. The luer 140 mates with the luer attachment fitting 250 by rotating the luer tapered fitting 254 into the luer 140 until recesses 142 engage the luer attachment projections 252. The luer 140 includes a male member 144 that is inserted in the body fluid passageway 238. The male member 144 engages the second actuator end 298 of the actuator 220. The engagement of the male member 144 with the second actuator end 298 causes the septum contact surface 312 of the actuator 220 to engage and press against the actuator recess 285 of the resilient septum 216. This causes the shoulder surface 284 to be disengaged from the septum shoulder 246 of the body 212. This breaks the seal between the shoulder surface 284 and the septum shoulder 246. As shown in Fig. 11, fluid is free to flow from the luer 140 through the fluid passageway 306 of the actuator 220 to the chamber fluid passageways 290 to the channels 278 through the end cap fluid passageway 264 and to the catheter fluid passageway 294 into the blood vessel. The assembly 10 can be resealed by removing the luer 140 from the second end 232 of the body 212 thereby causing the septum 216 to regain its original shape to form a seal between the shoulder surface 284 and the septum shoulder 246.

While the invention has been described with reference to preferred embodiments, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted for elements thereof without departing from the essential scope of the invention. In addition, many modifications may be made to adapt a

particular situation or material to the teachings of the invention without departing from the essential scope thereof. Therefore, it is intended that the invention not be limited to the particular embodiments disclosed as the best mode contemplated for carrying out this invention, but that the  
5 invention will include all embodiments falling within the scope of the claims.

CLAIMS

I claim:

1. A valve assembly comprising:
  - a body having a first end and a second end, said body
  - 5 defining a passageway extending between said first and second ends, said body defining a sealing surface in said passageway;
  - a resilient septum positioned in said passageway in sealing engagement with said sealing surface;
  - means for compressing said septum to disengage said
  - 10 septum from said sealing surface to allow fluid flow through said passageway.
2. The valve assembly of claim 1, wherein said assembly further includes a sharp extending through said passageway and said
- 15 septum.
3. A valve assembly comprising:
  - a body having a first end, a second end, an exterior surface and an interior surface, said interior surface defining a body fluid
  - 20 passageway extending between said first and second ends, said interior surface defining a chamber having a substantially cylindrical side wall adjacent said first end, said cylindrical side wall defining a plurality to fluid recesses, said interior surface defining a substantially annular septum shoulder adjacent said chamber;
  - 25 an end cap adjacent said first end of said body and in communication with said chamber, said end cap having an attachment end, a body end, an outer surface and an inner surface, said inner surface defining an end cap fluid passageway extending between said attachment end and said body end, said body end including a plurality of

spaced outwardly extending projections adjacent said end cap fluid passageway, said projections adjacent said chamber;

5 a resilient septum having a shoulder surface and an opposed projections surface, said septum having a substantially circular chamber wall extending between said shoulder and projections surfaces, said shoulder surface engaging said septum shoulder to form a seal, said projections surface engaging said projections, said chamber wall adjacent said cylindrical side wall of said chamber, said chamber wall and said fluid recesses forming a plurality of chamber fluid passageways;

10 actuator means positioned in said body fluid passageway adjacent said second end of said body for moving said shoulder surface of said septum away from said shoulder to allow fluid to flow through said body, chamber and end cap fluid passageways.

15 4. The valve assembly of claim 3, wherein said exterior surface of said body defines attachment means adjacent said second end.

5. The valve assembly of claim 3, wherein said cylindrical side wall defines at least one fluid recess.

20 6. The valve assembly of claim 3, wherein said interior surface of said body defines a substantially annular actuator shoulder in said body fluid passageway.

25 7. The valve assembly of claim 3, wherein said projections on said end cap encompass said end cap fluid passageway to form channels for channeling fluid to said end cap fluid passageway.

30 8. The valve assembly of claim 7, wherein said plurality of fluid recesses is in communication with said channels.

9. The valve assembly of claim 3, wherein said septum is compressible.

10. The valve assembly of claim 9, wherein said septum  
5 engages said cylindrical side wall of said body when compressed.

11. The valve assembly of claim 6, wherein said actuator means  
is comprised of an actuator body having a first actuator end, a second  
actuator end, an exterior actuator surface and an interior actuator  
10 surface, said interior actuator surface defining an actuator fluid  
passageway extending between said first actuator end and said second  
actuator end, said actuator exterior surface defining an annular septum  
contact surface and an opposed actuator shoulder contact surface, said  
septum contact surface engaging said septum, and said actuator shoulder  
15 contact surface engaging said actuator shoulder.

12. A valve assembly for use in establishing intravenous access  
to a blood vessel comprising:

a body having a first end, a second end, an exterior surface  
20 and an interior surface, said interior surface defining a body fluid  
passageway extending between said first and second ends, said interior  
surface defining a chamber having a substantially cylindrical side wall  
adjacent said first end, said cylindrical side defining a plurality of fluid  
recesses, said interior surface defining a substantially annular septum  
25 shoulder adjacent said cylindrical side wall;

an end cap adjacent said first end of said body and in  
communication with said chamber, said end cap having an attachment  
end, a body end, an outer surface and an inner surface, said inner  
surface defining an end cap fluid passageway extending between said  
30 attachment end and said body end, said body end including a plurality of

spaced outwardly extending projections adjacent said end cap fluid passageway, said projections adjacent said chamber;

5 a resilient septum having a shoulder surface and an opposed projections surface, said septum having a substantially circular chamber wall extending between said shoulder and projections surfaces, said shoulder surface engaging said septum shoulder to form a seal, said projections surface engaging said projections, said chamber wall adjacent said cylindrical side wall of said chamber, said chamber wall and said fluid recesses forming a plurality of chamber fluid passageways;

10 a catheter having a catheter fluid passageway extending therethrough positioned on said attachment end of said end cap;

an actuator having an actuator body including a first actuator end, a second actuator end, an exterior actuator surface and an interior actuator surface, said interior actuator surface defining an actuator fluid passageway extending between said first actuator end and said second actuator end, said first actuator end engaging said shoulder surface of said septum to seat and unseat said septum; and

15 a needle having a first needle end, a second needle end, a needle exterior surface and a needle interior surface, said needle interior surface defining a needle fluid passageway extending between said first needle end and said second needle end, said needle extending through said actuator fluid passageway, said septum, said end cap fluid passageway and said catheter fluid passageway.

20 13. The valve assembly of claim 12, wherein said cylindrical side wall defines at least one fluid recess.

25 14. The valve assembly of claim 12, wherein said projections on said end cap encompass said end cap fluid passageway to form channels for channeling fluid to said end cap fluid passageway.

30

15. The valve assembly of claim 14, wherein said plurality of fluid recesses is in communication with said channels.

5 16. The valve assembly of claim 12, wherein said septum is compressible.

17. The valve assembly of claim 16, wherein said septum engages said cylindrical side wall of said body when compressed.

10 18. The valve assembly of claim 16, wherein said septum is self-sealing upon removal of said needle from said septum.

15 19. The valve assembly of claim 12, wherein said needle includes handle means adjacent said second needle end.

20 20. The valve assembly of claim 19, wherein said handle means consists of a handle having a first end and a second end, said handle including a reciprocating handle member attached to said second needle end, said handle member causing said needle to move from said catheter fluid passageway, said end cap fluid passageway, said septum and said actuator fluid passageway when said handle member is moved from said first end toward said second end, whereby said needle is retracted into said handle.





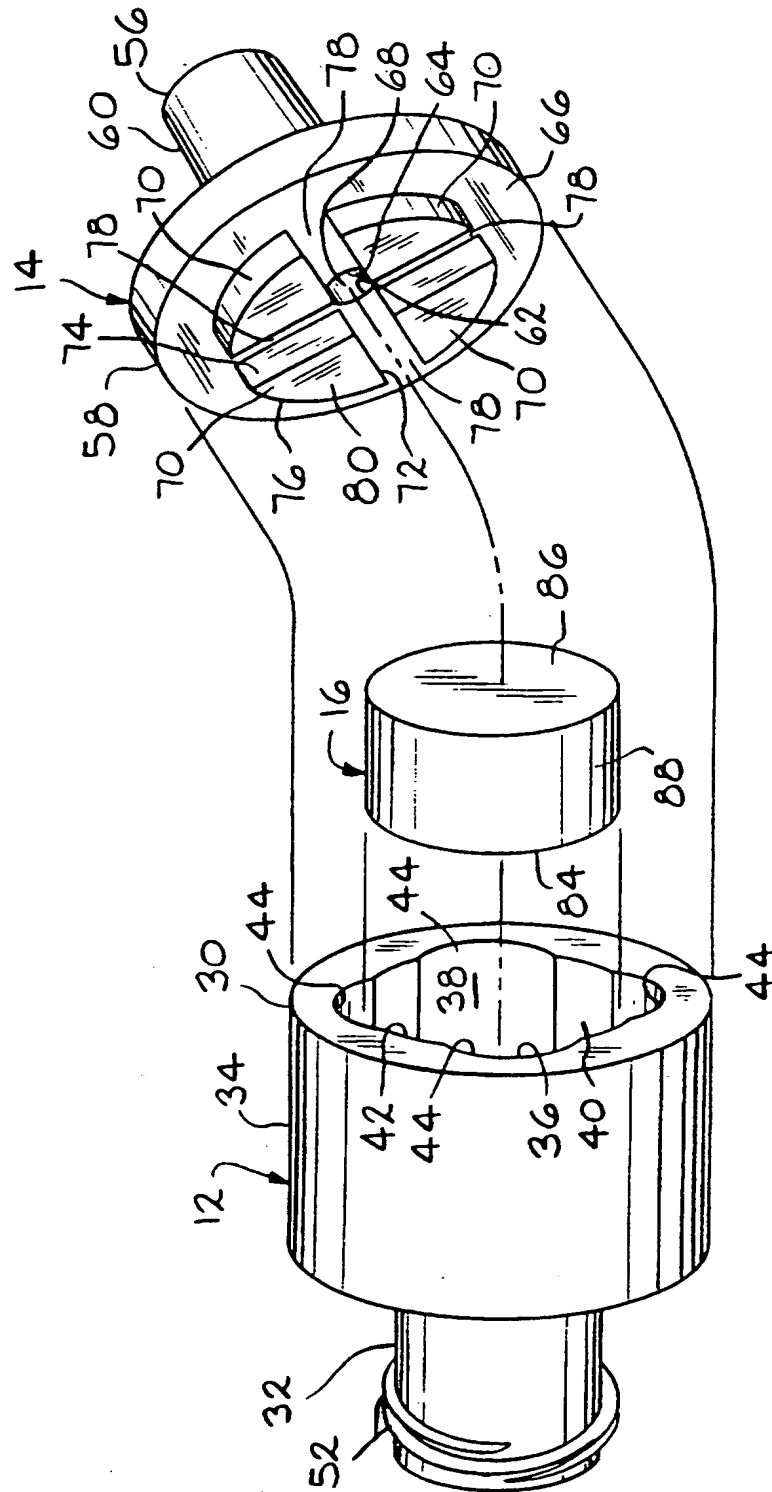
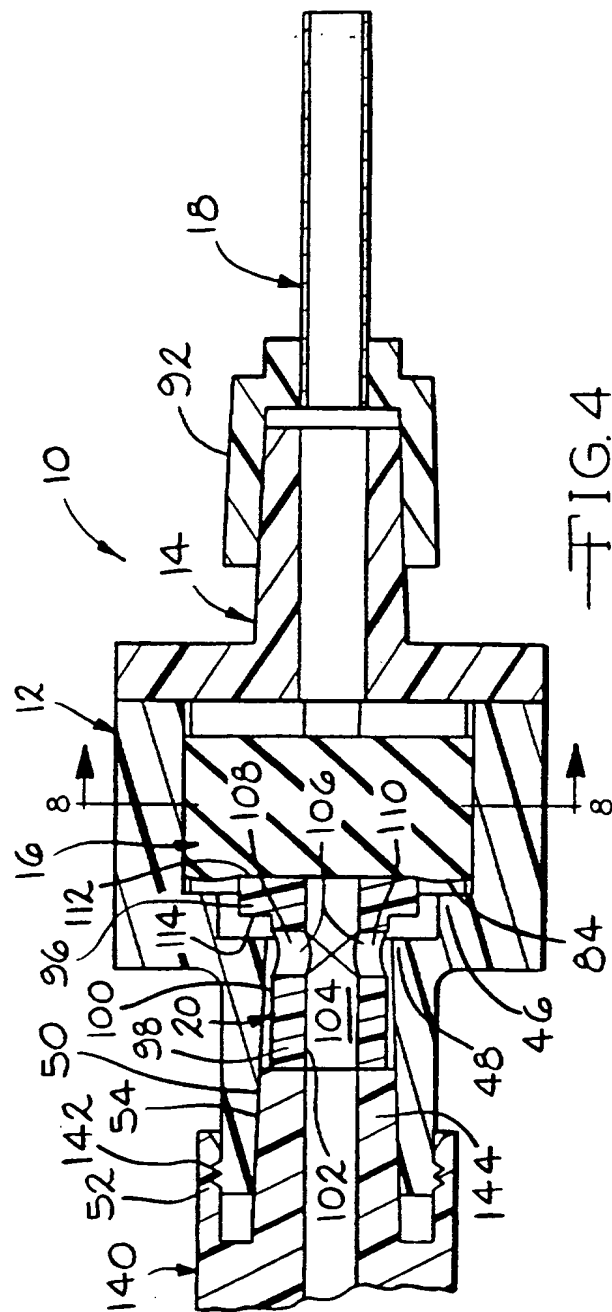
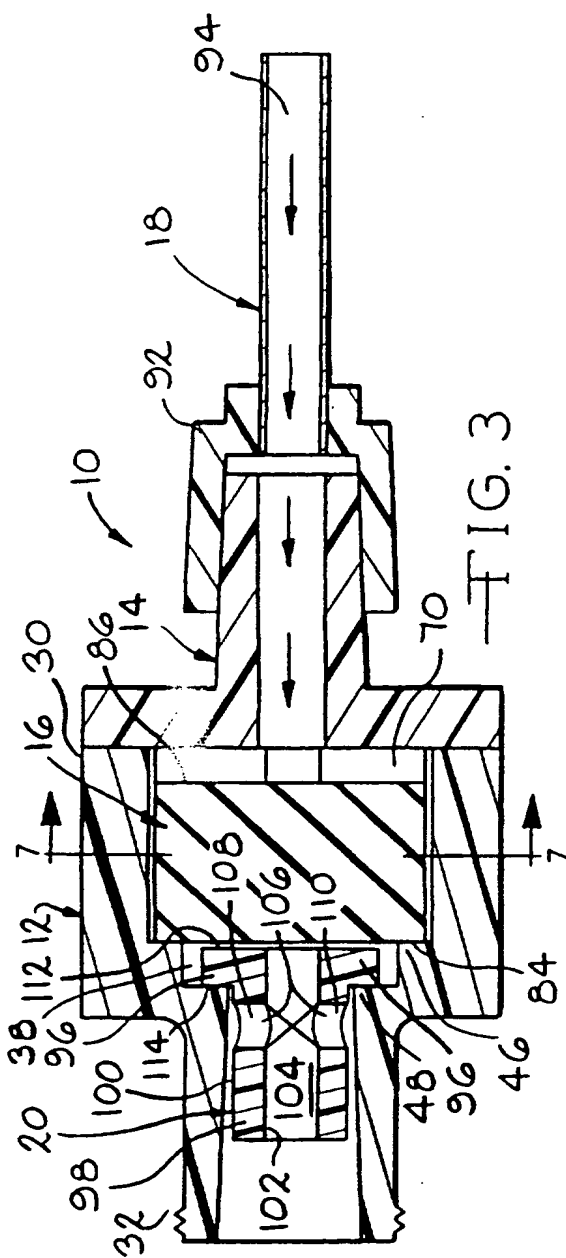
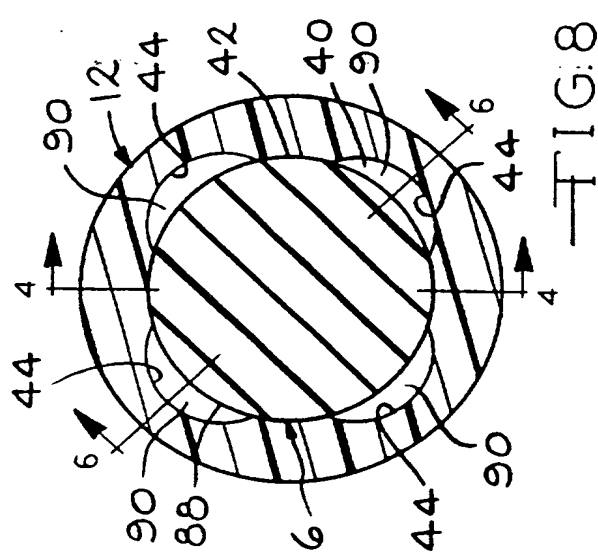
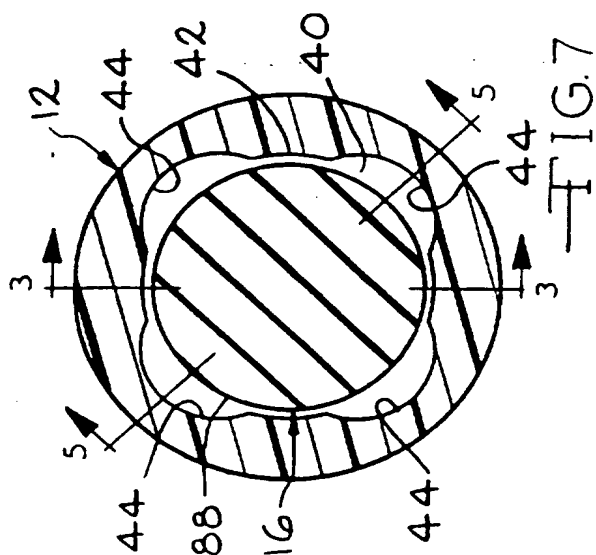
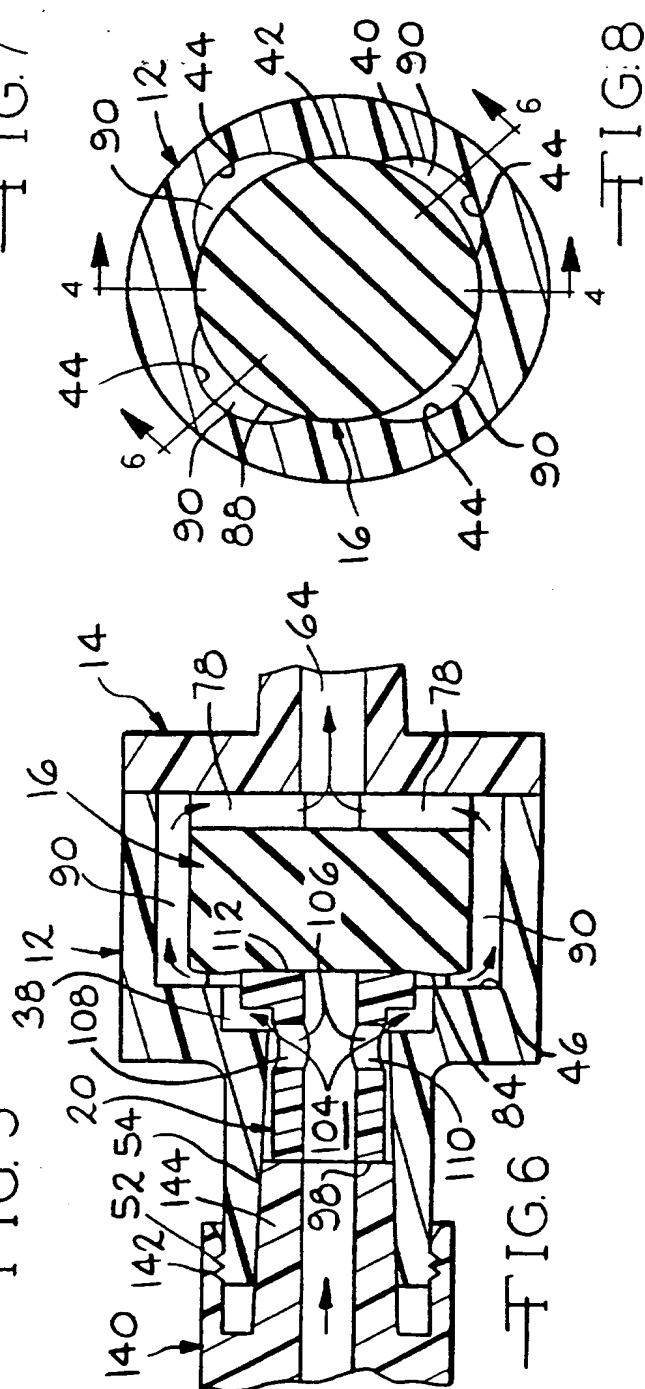
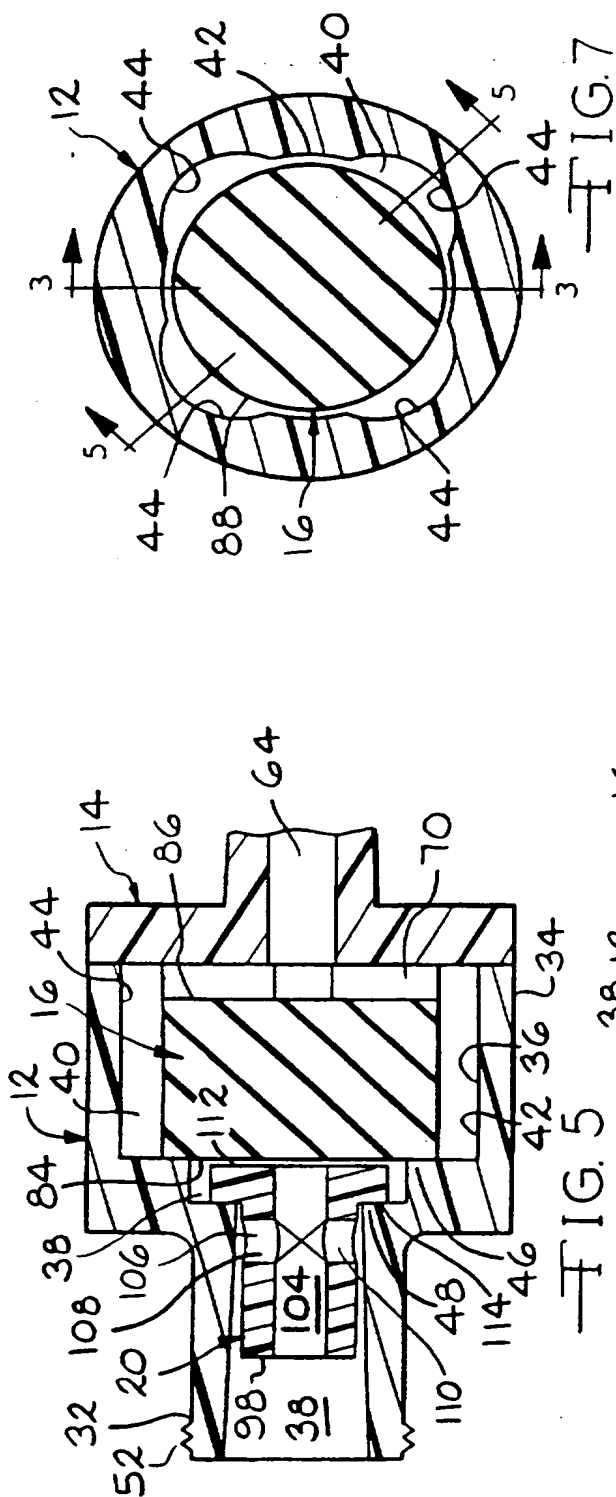


FIG. 2





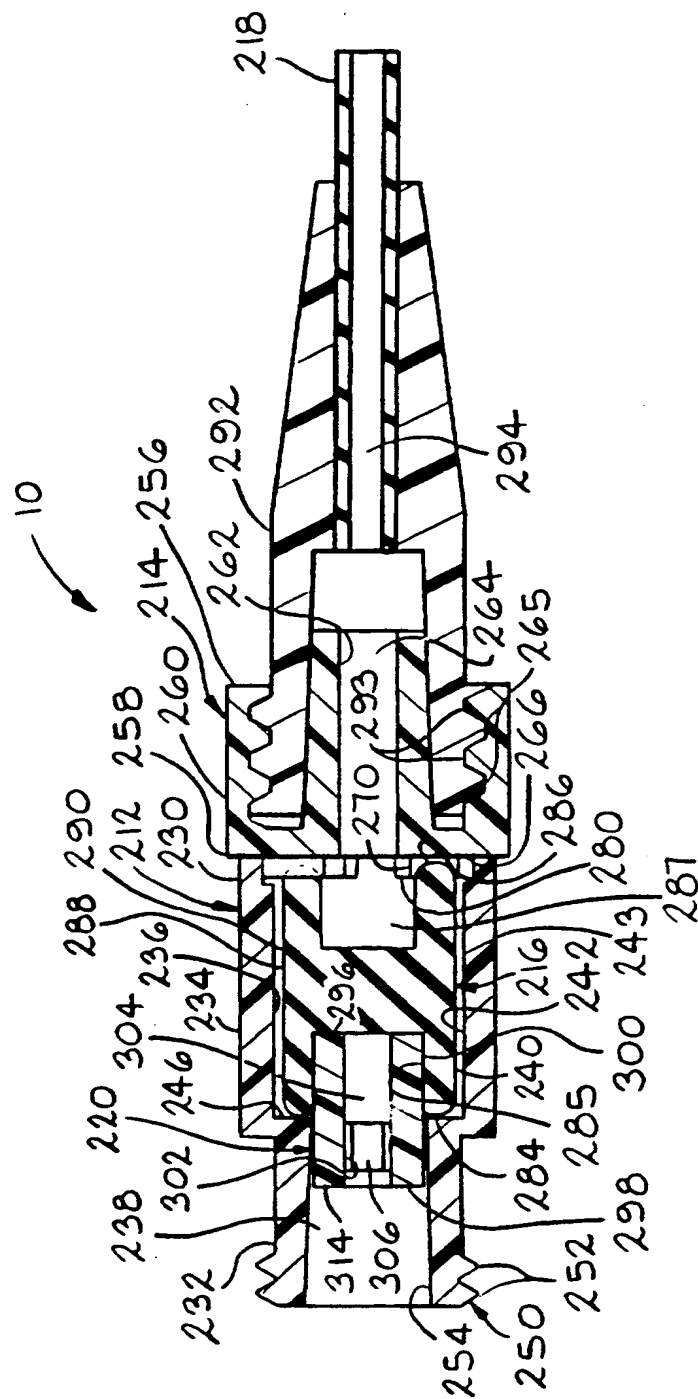
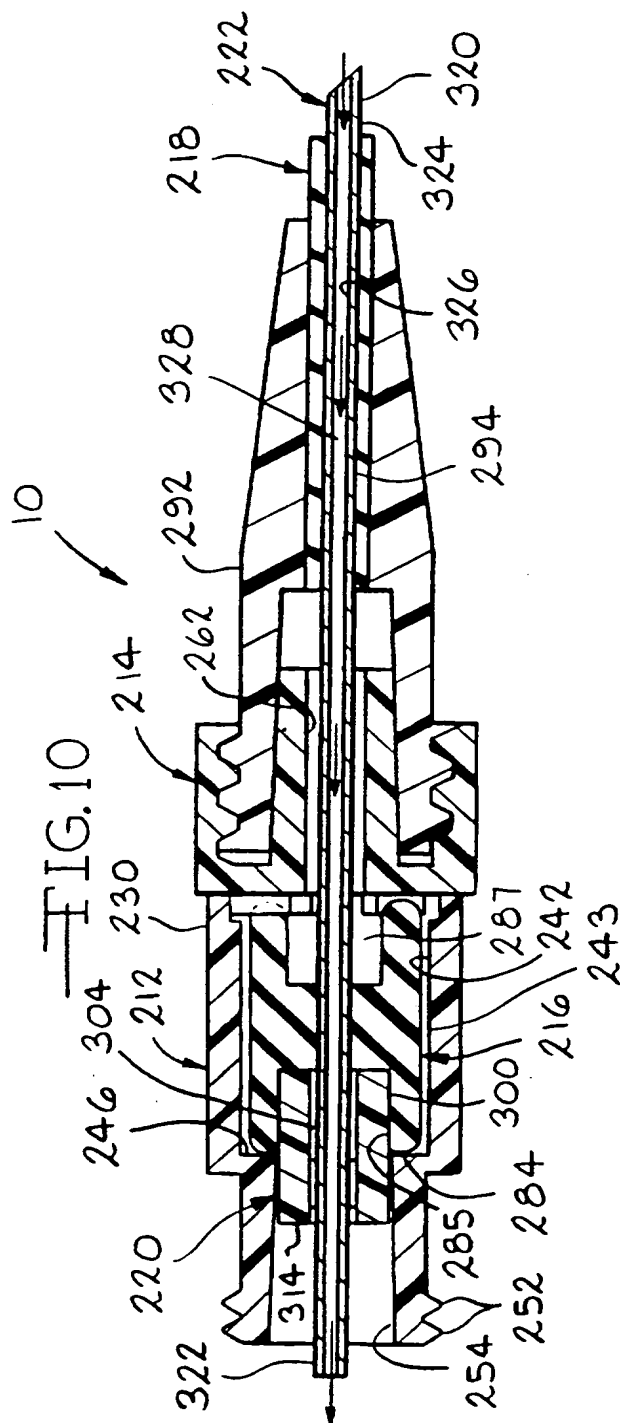
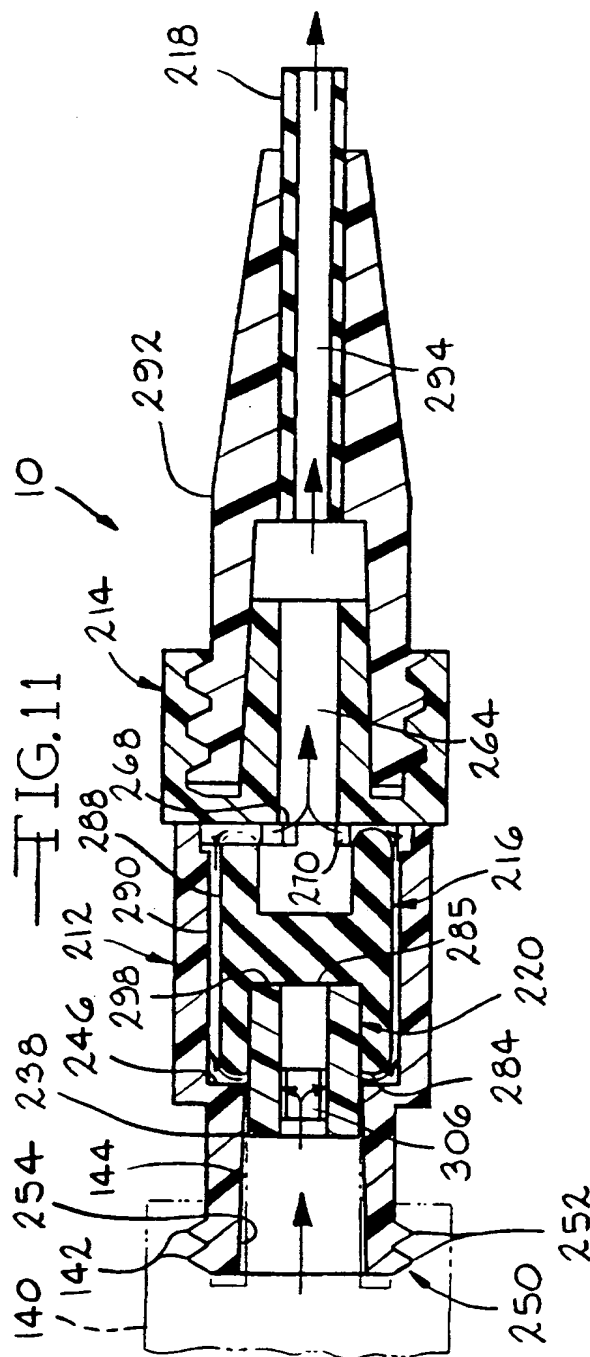


FIG. 9





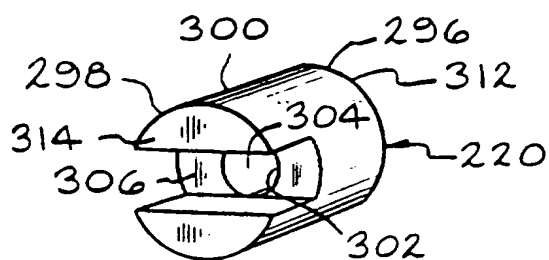


FIG. 12

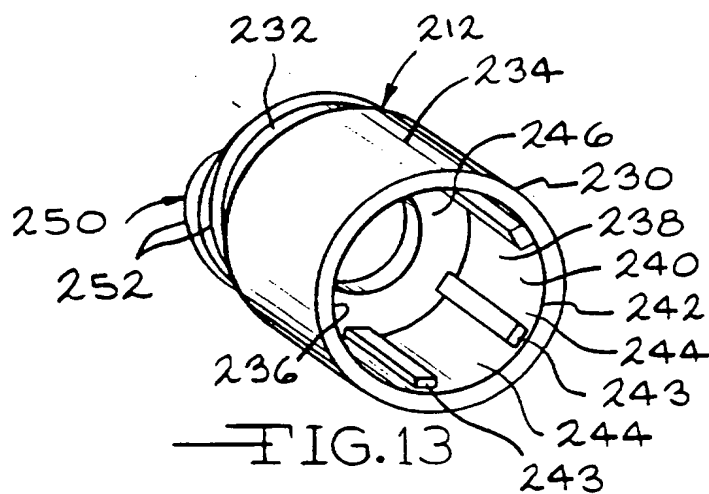


FIG. 13

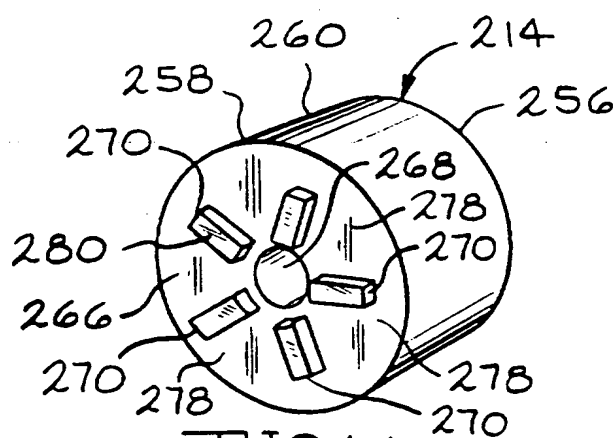
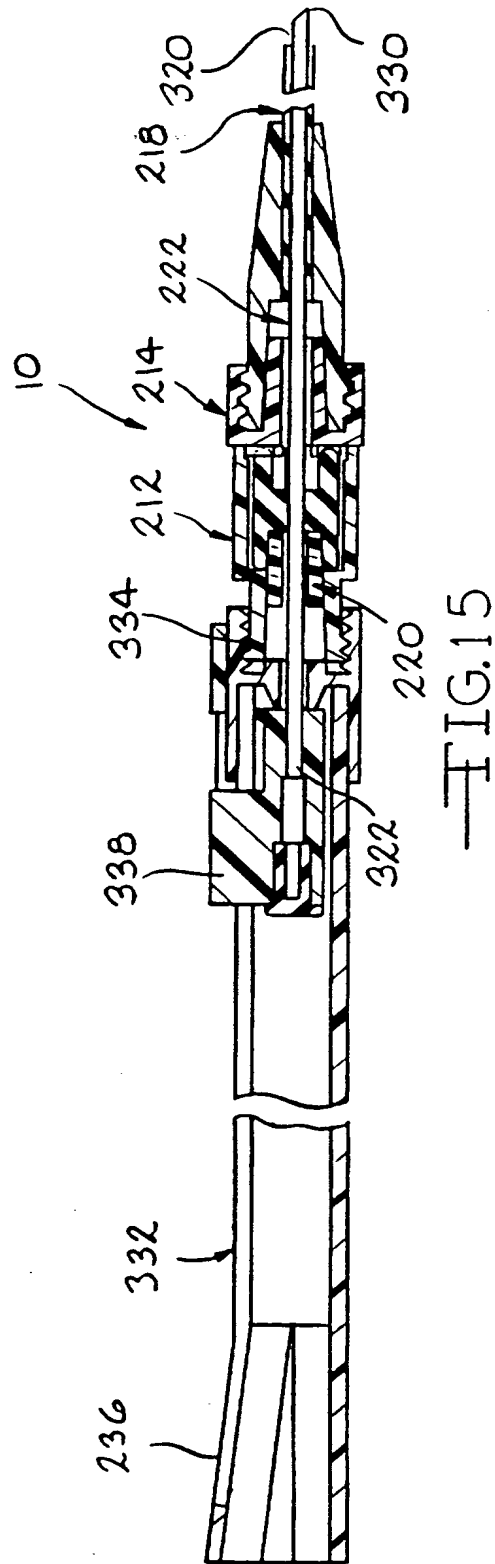


FIG. 14

9/9



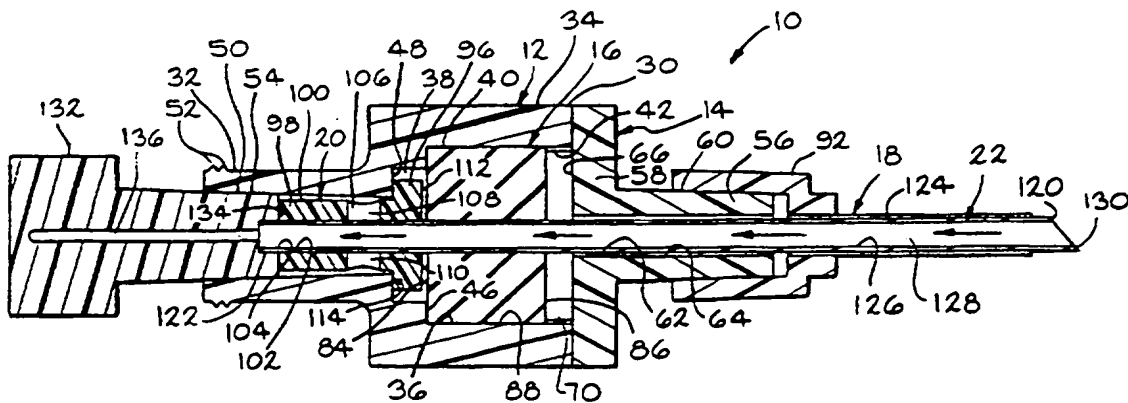




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61M 39/26, 39/06</b>		(11) International Publication Number: <b>WO 97/31676</b>
<b>A3</b>		(43) International Publication Date: 4 September 1997 (04.09.97)
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(30) Priority Data: 08/608,280 28 February 1996 (28.02.96) US		
(71) Applicant: AEROQUIP CORPORATION [US/US]; 3000 Strayer Road, Maumee, OH 43537 (US).		
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(74) Agents: SHUST, Nestor, W. et al.; Jones, Day, Reavis & Pogue, North Point, 901 Lakeside Avenue, Cleveland, OH 44114 (US).		(88) Date of publication of the international search report: 23 October 1997 (23.10.97)

(54) Title: VALVE ASSEMBLY FOR MEDICAL USES



## (57) Abstract

A valve assembly having a body, an end cap, a resilient septum, and an actuator. The body forms a plurality of fluid recesses. The end cap defines a plurality of projections that form channels. The septum is positioned between the body and the end cap. An actuator device is positioned adjacent the septum for moving the septum away from a shoulder defined in the body to allow fluid to pass through the body, actuator, and end cap. The assembly can include a sharp. The sharp extends through the body, the actuator, the septum and the end cap.

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# INTERNATIONAL SEARCH REPORT

Internat. Application No  
PCT/US 97/02199

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61M39/26 A61M39/06

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 696 461 A (BECTON DISCKINSON AND COMPANY) 14 February 1996 see column 8, line 29 - line 30 see claims 1,8; figures 2,4 ---	1-11
X	GB 1 466 242 A (METABURN (HOLDINGS) LIMITED) 2 March 1977 see claim 1; figures ---	1
A	---	3,5
X	US 5 390 898 A (SMEDLEY ET AL.) 21 February 1995 see claim 1; figures 3,4 ---	1
A	---	3,7
X	US 4 421 296 A (STEPHENS) 20 December 1983 see claim 1; figures 1,2 ---	1
	-/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search  19 June 1997	Date of mailing of the international search report  11.09.97
Name and mailing address of the ISA European Patent Office, P.B. 5818 PatentAan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+ 31-70) 340-3016	Authorized officer  SEDY R.

# INTERNATIONAL SEARCH REPORT

Internat. Application No  
PCT/US 97/02199

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 440 479 A (CRITIKON, INC.) 7 August 1991 -see figure 4A ---	2
A	EP 0 332 884 A (B. BRAUN MELSUNGEN) 20 September 1989 see column 3, line 8 - line 13 see column 3, line 55 - line 57 see figure 1 ---	3
A	EP 0 356 679 A (ING. ERICH PFEIFFER GMBH & CO. KG) 7 March 1990 see column 6, line 36 - line 54 see figure 3 -----	7,8

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 97/ 02199

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
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## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. Claims : 1-11  
Valve assembly.
2. Claims : 12-20  
Valve assembly with a catheter and a needle.

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
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1-11

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat. Application No

PCT/US 97/02199

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